

AMENDMENT

Please replace presently pending claims 1-24 with the following claims 1-24:

1. Agglomerates in crystalline form comprising one or more β -lactam compounds, wherein at least one β -lactam compound has a high water affinity, and optionally containing one or more excipients, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

2. Agglomerates according to claim 1, wherein the agglomerates are substantially free from non-agglomerated β -lactam crystals.

3. (Amended) Agglomerates according to claim 1, wherein at least one β -lactam compound is clavulanic acid.

4. (Amended) Agglomerates according to claim 1, wherein the β -lactam compound is potassium clavulanate.

5. Agglomerates according to claim 4, consisting of only potassium clavulanate.

6. Agglomerates according to claim 4 further comprising amoxicillin.

7. (Amended) Agglomerates according to claim 1, wherein the one or more excipients are selected from the group consisting of microcrystalline cellulose and silica.

8. (Amended) Agglomerates according to claim 1, wherein the agglomerates have an average particle size between about 1 μm and 1500 μm .

9. (Amended) Agglomerates according to claim 1 in sterile form.

10. (Amended) A process for the preparing the crystallised agglomerates of claim 1, which comprises stirring at least one β -lactam in a liquid phase.

11. (Amended) A process according to claim 10, wherein the liquid phase comprises a solvent or in a mixture of solvents together with one or more anti-solvents.

12. (Amended) A process according to claim 11, wherein the ratio of the weight of the solvent containing β -lactam to the anti-solvent is about 0.05 to 10 wt.%.
A2
Sub
B1

13. (Amended) A process according to claim 11, wherein the solvent is selected from the group consisting of water, alcohol, ketone and ester or a mixture thereof, wherein water is present in said mixture.

14. (Amended) A process according to claim 10, wherein the anti-solvent is a ketone, an ester, or an alcohol, or a mixture of these anti-solvents, optionally containing water.

Please cancel claim 15.

16. (Amended) A process according to claim 10, wherein the stirring is performed by applying stirring devices in one or more vessels, in-line mixers or a combination thereof.

17. (Amended) A process according to claim 16, wherein the stirring device is a high shear mixer.
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18. (Amended) A process according to claim 25, wherein said stirring is performed by combining and permuting different stirring devices, the speeds of said devices, the type and amount of the solvents used, and mixing one or more solvents and anti-solvents.

19. (Amended) A process according to claim 18, wherein the agglomerates have various particle sizes.

20. (Amended) A process according to claim 11, wherein the process comprises dissolving one or more β -lactams in a solvent, adjusting the pH to about neutral and mixing with the anti-solvent.

21. (Amended) A pharmaceutical formulation comprising the agglomerates of claim 1 and one or more pharmaceutically acceptable excipients.

22. (Amended) A pharmaceutical formulation comprising the crystalline agglomerates of potassium clavulanate of claim 5, amoxicillin and optionally one or more pharmaceutically acceptable inert excipients.

23. (Amended) The pharmaceutical formulation of claim 22 which contains one or more pharmaceutically acceptable inert excipients selected from the group consisting of microcrystalline cellulose and silica.

24. (Amended) A pharmaceutical dosage form comprising a pharmaceutical formulation of claim 21.

Please add the following claims 25-26:

25. (New) A process according to claim 16, wherein the liquid phase comprises a solvent or in a mixture of solvents together with one or more anti-solvents.

26. (New) A pharmaceutical dosage form comprising a pharmaceutical formulation of claim 22.